IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

URL PHARMA, INC., ET AL.,

Plaintiffs, : CIVIL ACTION

.

v. : 15-505

:

RECKITT BENCKISER, INC.,

:

Defendant.

MEMORANDUM OPINION

Tucker, C.J. August 25, 2015

Presently before the Court are Defendant Reckitt Benckiser, Inc.'s ("Reckitt") Motion to Dismiss Plaintiffs' Complaint Pursuant to Rules 8(a) and 12(b)(6) (Doc. 20), Plaintiffs URL Pharma, Inc., Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc.'s (collectively "Mutual") Response in Opposition to Reckitt's Motion to Dismiss (Doc. 21), and Defendant Reckitt's Reply Memorandum of Law in Further Support of Its Motion to Dismiss (Doc. 24). Upon careful consideration of the parties' briefs, exhibits, and all other papers herein, and for the reasons set forth below, this Court *denies* Reckitt's Motion to Dismiss Plaintiffs' Complaint in part and *grants* Reckitt's Motion in part.

FACTUAL BACKGROUND

Mutual brings the instant civil antitrust action for injunctive relief and damages against Reckitt alleging violations of the Sherman Antitrust Act and the Clayton Antitrust Act. Reckitt owns the patent for an over-the-counter drug, extended-release guaifenesin ("ERG"), and sells it under the brand name Mucinex® ("Mucinex ERG"). Guaifenesin is an expectorant that thins bronchial secretions to clear the bronchial passageways of mucus in order to make coughs more

productive. Compl. ¶ 17. Reckitt's Mucinex ERG was the only ERG product consumers could purchase at the relevant periods. However, other immediate release guaifenesin ("IRG") products were available.

Prior to the instant action, Mutual had planned to manufacture and sell a generic version of ERG, but Reckitt sued Mutual in 2006 for patent infringement. The parties entered into a settlement agreement ("Settlement Agreement") in March 2007 wherein Mutual agreed to refrain from entering the ERG market until, <u>inter alia</u>, another generic manufacturer began offering generic ERG to the public. The relevant terms of the 2007 Settlement Agreement are as follows:

5. (a) *Mutual 600 mg Guaifenesin Product*: Subject to Section 5(b) below, the Marketing License Effective Date for the Mutual 600 mg Guaifenesin Product shall be the later of (i) July 1, 2012 or (ii) the date Mutual obtains [Food and Drug Administration] FDA approval to market such Licensed Product.

. . . .

(ii) If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation or Adams Guaifenesin Product, then the Marketing License Effective Date shall be the date on which Mutual obtains FDA approval to market such Licensed Product corresponding to such FDA-approved Third Party Formulation. Mutual, in its sole discretion, may purchase from Adams and Adams shall supply, pursuant to the terms of Section 6 of this Agreement, tablets of the Adams Guaifenesin Product corresponding to such Third Party Formulation, for sale by Mutual, its Affiliates or a single independent Sublicensee to the Retail Trade under a private label or a brand name other than Adams' brand names for the Adams Guaifenesin Product, in the Territory Date. To the extent that Mutual purchases tablets of Adams Guaifenesin Product pursuant to the Supply Agreement, Adams grants Mutual a non-exclusive, perpetual and irrevocable right to sell and offer for sale to the Retail Trade such tablets supplied by Adams under the Licensed Patents in the Territory and agrees, in a timely manner, to take all steps with respect to the New Drug Applications and/or other marketing authorizations for such Adams Guaifenesin Product that are necessary in order

¹ Adams Respiratory Therapeutics, Inc., Adams Respiratory Operations, Inc., and Adams Respiratory Products, Inc. (collectively "Adams") merged into Reckitt sometime after the execution of the Settlement Agreement. Compl. ¶ 20; <u>id.</u> at Ex. B. As a consequence of the merger, Reckitt assumed the rights and obligations of Adams under the Settlement Agreement. Compl. ¶ 20; id. at Ex. B.

to manufacture and supply such Adams Guaifenesin Product tablets to Mutual hereunder and under the Supply Agreement and to ensure that Mutual and its Affiliates or its single Sublicensee, as the case may be, is authorized to sell such Adams Guaifenesin Product. . . .

6. (a) Mutual shall notify Adams in writing of its election to purchase tablets of Adams Guaifenesin Product pursuant to Section 5(b)(ii), and the Parties shall promptly execute a supply agreement. . . . The tablets supplied by Adams shall be white and/or in such other reasonable mono-colored configuration mutually agreeable to the Parties, and shall be manufactured using Adams' and its Affiliates' bilayered technology.

Compl., Ex. A. §§ 5, 6 (emphasis added), Settlement Agreement. The Launch Date was defined in § 5(b)(i) as "the **actual date of first lawful commercial sale** of a formulation corresponding to the Licensed Product in such Third Party Launch Notice by . . . a Third Party" (emphasis added). Thus, pursuant to the Settlement Agreement, if Mutual failed to obtain FDA approval to market its generic ERG product, then after a third party launched a third-party formulation of the ERG product, Mutual could arrange to execute a supply agreement with Reckitt. The supply agreement would allow Mutual to purchase from Reckitt tablets corresponding to the third-party formulation of the ERG product.

The Settlement Agreement also provided that no adequate remedy at law exists for damages which either party may sustain resulting from breach of the Settlement Agreement. Settlement Agreement § 26. The parties agreed that in the event of a breach, the nonbreaching party would be entitled to specific performance of the contractual obligations. <u>Id.</u>

Mutual alleges that by October 2013, a third party, Perrigo Company PLC ("Perrigo"), had been selling and delivering a generic version of Mucinex ERG. Compl. ¶ 22. Mutual had not obtained FDA approval to market an ERG product by this time. Accordingly, Mutual argues that Perrigo's entry into the market with the generic ERG product triggered Reckitt's obligation to supply Mutual with Reckitt's ERG product corresponding to Perrigo's ERG formulation. Mutual

claims that on October 24, 2013, pursuant to the Settlement Agreement, Mutual provided Reckitt written notice that it was electing to purchase for resale the generic equivalent of Mucinex ERG from Reckitt.

Mutual claims that Reckitt has engaged in anticompetitive behavior by continuously refusing to and expressly repudiating its obligation to supply Mutual with the requested tablets. Mutual asserts that Reckitt's refusal to supply ERG harms both Mutual and consumers of ERG by extending Reckitt's monopoly in the ERG market. According to Mutual, if Reckitt had abided by the terms of the Settlement Agreement, Mutual could have entered the market with a generic ERG product that would have generated product and price competition economically benefiting consumers. See Compl. ¶ 27.

In Count I of its Complaint, Mutual alleges monopolization in violation of the Sherman Antitrust Act, 15 U.S.C. § 2, and the Clayton Antitrust Act, 15 U.S.C. § 15, and requests treble damages. Count II of Mutual's Complaint brings a claim for monopolization under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. § 26, and requests injunctive relief in the form of specific performance. Count III brings claims for attempted monopolization in violation of the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and requests treble damages and injunctive relief in the form of specific performance. Counts IV and V of the Complaint assert a breach of contract claim and requests direct and consequential damages, as well as specific performance. Count VI seeks declaratory judgment as to the validity of the Settlement Agreement and Reckitt's duty to perform pursuant to the parties' Settlement Agreement.

Reckitt moves to dismiss Mutual's Complaint pursuant to Federal Rules of Civil

Procedure 8(a) and 12(b)(6) arguing that (1) Mutual fails to state a claim under Section 2 of the

Sherman Act; (2) Mutual fails to plead a relevant product market; (3) Mutual has not suffered antitrust injury and cannot demonstrate antitrust standing; (4) Mutual's state law claims fail as a matter of law; and (5) Mutual's claim for declaratory judgment is not ripe. Reckitt urges the Court to decline to exercise supplemental jurisdiction over Mutual's state law claims if the Court dismisses Mutual's federal antitrust claims. For the reasons set forth below, this Court denies Reckitt's Motion as to the antitrust and state law claims, but grants Reckitt's Motion as to Mutual's claim for declaratory judgment regarding third-party formulations, which have not yet received FDA approval.

STANDARD OF REVIEW

A court may dismiss a plaintiff's complaint under Rule 12(b)(6) only when it does not state a claim for relief that is "plausible on its face." Santiago v. Warminster Twp., 629 F.3d 121, 128 (3d Cir. 2010) (quoting Sheridan v. NGK Metals Corp., 609 F.3d 239, 262 n.27 (3d Cir. 2010)). All well-pleaded factual allegations contained in a plaintiff's complaint must be accepted as true and must be interpreted in the light most favorable to the plaintiff. Argueta v. U.S. Immigration & Customs Enforcement, 643 F.3d 60, 74 (3d Cir. 2011). A complaint is plausible on its face when its factual allegations allow a court to draw a reasonable inference that a defendant is liable for the harm alleged. Santiago, 629 F.3d at 128.

To determine the sufficiency of a complaint, courts of the Third Circuit are required to perform a three-step analysis. <u>Id.</u> at 130. First, a court must identify plaintiff's claims and determine the required elements of those claims. <u>Id.</u> Next, a court must identify, and strike, conclusory allegations contained in plaintiff's complaint. <u>Id.</u> Conclusory allegations are those that are no more than "an unadorned, the-defendant-unlawfully-harmed-me accusation, labels and conclusions, a formulaic recitation of the elements of a cause of action, or naked

assertion[s]." <u>Argueta</u>, 643 F.3d at 72 (quoting <u>Ashcroft v. Iqbal</u>, 556 U.S. 662, 678 (2009)) (internal quotation marks omitted). Finally, a court must determine if the remaining factual allegations, "plausibly give rise to an entitlement for relief." <u>Id.</u> at 73.

The focus of a court's inquiry into the sufficiency of a plaintiff's complaint is always plausibility of relief. <u>Bistrian v. Levi</u>, 696 F.3d 352, 365 (3d Cir. 2012). Plausibility does not require a plaintiff's complaint to demonstrate entitlement to relief is likely or probable. <u>Argueta</u>, 643 F.3d at 72.

A plaintiff's complaint must only plead facts sufficient "to raise a reasonable expectation that discovery will reveal evidence of the necessary element." McTernan v. City of York, Pa., 564 F.3d 636, 646 (3d Cir. 2009) (citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007)). "A complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." McTernan, 564 F.3d at 646 (citing Twombly, 550 U.S. at 555-56).

At the motion to dismiss stage, the standard for dismissal for antitrust claims is higher.

Sheet Metal Duct, Inc. v. Lindab, Inc., No. CIV. A. 99-6299, 2000 WL 987865, at *2 (E.D. Pa. July 18, 2000). Courts liberally construe antitrust complaints at this stage of the proceeding. See Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 179 (3d Cir. 1988).

"[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators,' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." Hosp. Bldg. Co. v. Trustees of Rex Hosp., 425 U.S. 738, 746 (1976) (quoting Poller v. Columbia Broad., 368 U.S. 464 (1962)). Still, the antitrust plaintiff must allege facts sufficient to overcome a Rule 12(b)(6) motion. See Zimmerman, 836 F.2d at 179.

DISCUSSION

The Sherman Act was enacted "to protect the public from the failure of the market." Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993). Mutual has asserted claims of monopolization and attempted monopolization under Section 2 of the Sherman Act against Reckitt. Section 2 of the Sherman Act makes it unlawful "to monopolize, or attempt to monopolize, . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2. The Clayton Act includes the Sherman Act as one of the applicable antitrust laws and allows a person "threatened [with] loss or damage by a violation of the antitrust laws to seek injunctive relief." In re Neurontin Antitrust Litig., Nos. 02-1830 (FSH), 02-2731 (FSH), 2009 WL 2751029, at *8 (D.N.J. Aug. 28, 2009) (internal quotation marks and citations omitted). Mutual has also requested injunctive relief in the form of specific performance pursuant to the Clayton Act. In addition to its antitrust claims, Mutual also brings claims for breach of contract against Reckitt.

I. Mutual's Antitrust Claims – Monopolization and Attempted Monopolization

Mutual alleges that Reckitt (1) acquired and/or maintained monopoly power in the market for ERG in the United States through exclusionary, anticompetitive conduct, including withholding supply of ERG and (2) attempted to preserve monopoly power in the market for ERG. Reckitt asserts that Mutual's claims for monopolization and attempted monopolization fail because Mutual's definition of the relevant market is insufficient and Mutual has not suffered antitrust injury.

A. Mutual's Monopolization Claim

To prevail on a monopolization claim under Section 2 of the Sherman Act, a plaintiff must show: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a

Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 437 (3d Cir. 1997). Monopoly power alone will not be found unlawful unless it is accompanied by an element of anticompetitive conduct. Verizon Comme'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004). Anticompetitive conduct, also called exclusionary conduct, is required for both monopolization and attempted monopolization claims. Behrend v. Comcast Corp., No. 03-6604, 2012 WL 1231794, at *19 (E.D. Pa. Apr. 12, 2012).

"[M]onopoly power may be proven through direct evidence of supracompetitive prices and restricted output" or "inferred from the structure and composition of the relevant market."

Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007) (internal citations and quotation marks omitted). To support an inference of monopoly power, a plaintiff must plead and prove that the defendant has a dominant share in a relevant market and that significant barriers to entry protect that market. Id. (citing Harrison Aire, Inc. v. Aerorstar Int'l, Inc., 423 F.3d 374, 381 (3d Cir. 2005)). Entry barriers include regulatory and legal license requirements, high capital costs, or technological obstacles that prevent new competition from entering a market. Id.

1. Direct Evidence of Monopoly Power

Mutual contends that it has pled monopoly power by presenting direct evidence of Reckitt's supracompetitive prices—prices above competitive levels. "To support a claim that defendants set supra-competitive prices, antitrust plaintiffs must provide an analysis of the defendant's costs, and show that the defendant had an abnormally high price-cost margin and that they restricted output." Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 WL 1736957, at *7 (E.D. Pa. Apr. 16, 2015) (quoting Carpenter Tech. Corp. v. Allegheny Techs. Inc., No. 082907, 2011 WL 4528303, at *12 (E.D. Pa. Sept. 30, 2011)) (quotation marks

omitted). Mutual compares the price for Mucinex ERG before and after December 2014 when Perrigo entered the market. Before December 2014, Reckitt sold Mucinex ERG for 77 cents per pill at CVS. Compl. ¶ 34. After Perrigo entered the market, Reckitt reduced its prices by sixteen percent, selling Mucinex ERG for 65 cents per pill. <u>Id.</u>

Despite having pled these facts, Mutual has failed to provide direct evidence of Reckitt's monopoly power. Absent from Mutual's Complaint are any factual pleadings pertaining to Reckitt's price-costs margins or restricted output. Without evidence of **both** supracompetitive prices and restricted output, Mutual fails to offer direct evidence sufficient to establish Reckitt's market power. See, e.g., Broadcom, 501 F.3d at 307; Mylan Pharm., 2015 WL 1736957, at *7. Accordingly, Mutual must produce circumstantial evidence to support its assertion that Reckitt possessed monopoly power in the ERG market.

2. Indirect Evidence of Monopoly Power

To find circumstantial evidence of monopoly power, courts often examine market structure. Harrison Aire, 423 F.3d at 381. Plaintiffs bear the burden of defining the relevant market, which may be a fact-intensive endeavor. Queen City, 124 F.3d at 436 (citing Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 482 (1992)). Plaintiffs must also show that defendants held a dominant share of the market and that high barriers to entry existed. Harrison Aire, 423 F.3d at 381.

a. Relevant Market

The relevant product market is determined by examining "the reasonable interchangeability of use or the cross-elasticity of demand between the product itself" and its substitutes. <u>Brown Shoe Co. v. U.S.</u>, 370 U.S. 294, 325 (1962). "Interchangeability implies that one product is roughly equivalent to another for the use to which it is put; while there may be

Some degree of preference for the one over the other, either would work effectively." Queen City, 124 F.3d at 437 (quoting Allen-Myland, Inc. v. Int'l Bus. Mach. Corp., 33 F.3d 194, 206 (3d Cir. 1994)). Courts consider the price, use, and quality of the products. Id. Cross-elasticity of demand is "defined as the degree by which the amount of a product purchased will change in response to changes in its price." SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063 (3d Cir. 1978). For example, if the price of one of two substitutes decreases while the other remains constant, sales for the constant-priced product will decrease. A relevant product market describes those groups of producers that have the actual or potential ability to take significant amounts of business away from each other because of the similarity of their products. Id. "A market definition must look at all relevant sources of supply, either actual rivals or eager potential entrants to the market." Id.

Courts may dismiss a case where the plaintiff fails to plead a legally sufficient relevant market:

Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted.

Queen City, 124 F.3d at 436.

Here, Mutual contends that the relevant product market is the market for ERG products, a single product market. Compl. ¶ 29. Mutual supports this assertion by first arguing that guaifenesen drugs are shelved separate and apart from other cold and flu remedies, thereby demonstrating their unique therapeutic features. Id. at ¶ 30. Secondly, Mutual distinguishes guaifenesin products from other cold remedies, claiming that alternative remedies are ineffectual

or may cause side effects not associated with guaifenesin. <u>Id.</u> at ¶ 31. Next, Mutual argues that Mucinex ERG is marketed as providing 12-hours of symptom relief whereas IRG products provide only short-term relief and must be taken every three to four hours or the patient will experience symptom rebound. <u>Id.</u> at ¶ 32. Therefore, IRG is an unacceptable substitute for ERG. Finally, Mutual contends that Reckitt's ability to charge monopoly prices for Mucinex ERG demonstrates that ERG constitutes a separate market than IRG. Mutual claims that in November 2014, Reckitt charged consumers 43 cents per pill for Mucinex ERG while consumers of IRG were charged approximately 11 cents per pill. <u>Id.</u> at ¶ 33.

Reckitt counters that Mutual's definition of the relevant market is legally insufficient, as it fails to encompass all interchangeable substitutes. Reckitt asserts that other guaifenesin products, as well as other cough and cold remedies, could be substituted for ERG. Reckitt urges the Court to dismiss Mutual's Complaint for this alleged shortcoming.

Accepting Mutual's factual allegations as true, this Court finds that Mutual has satisfactorily pled a relevant market. The Supreme Court has held that a single product may, in some cases, constitute a separate relevant market when that product is sufficiently unique that no reasonable substitutes exist for the consumer. See Eastman Kodak Co., 504 U.S. at 482; see also SmithKline, 575 F.2d at 1064 (affirming lower court opinion that the relevant market consisted of cephalosporin antibiotic and not other general antibiotics because of its unique features such as level of toxicity and effectiveness, which made it inappropriately interchangeable with general antibiotics). Lower courts have also concluded that a single brand of a drug and its generic can fall within the same relevant market. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 388-89 (D. Ma. 2013) (concluding that the relevant market consisted of the brand and generic drug alone); In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 680-81

(E.D. Mich. 2000) (accepting plaintiffs' pleadings that a single brand of a drug and its generic bioequivalents constituted the relevant market).

Here, Mutual alleges that ERG is unique and has no reasonable substitutes. <u>See</u> Compl. ¶¶ 30-33, 36. Determining the accuracy of Mutual's characterization of the reasonable interchangeability of ERG with other drugs is a fact-intensive inquiry not properly addressed in a Rule 12(b)(6) motion to dismiss. <u>See Eastman Kodak</u>, 504 U.S. at 482 (observing that the proper market definition "can be determined only after a factual inquiry into the 'commercial realities' faced by consumers"). As such, this Court denies Reckitt's Motion to Dismiss Mutual's Complaint for failure to plead a relevant market.

b. Dominant Share and Barriers to Entry

Next, to demonstrate Reckitt's monopoly power in the relevant market, Mutual must also show that Reckitt held a dominant share of the market and significant barriers to entry existed. The parties do not dispute that Reckitt has a monopoly over Mucinex ERG arising from Reckitt's patent. See Reckitt's Mem. of Law In Support of Mot. to Dismiss at 7 ("[Reckitt] holds the Mucinex ERG Patents and, thus, has a lawful patent monopoly over its product."). Although Mutual has not indicated the percentage of the market for ERG dominated by Reckitt, Mutual has stated that Perrigo's presence in the market has been limited. See Compl. ¶ 35. Moreover, patents grant the patentee "the exclusive right to manufacture, use, and sell his invention" and exclude potential competitors from utilizing the invention without the patentee's consent. Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135. Patents, therefore, present one

significant barrier to entry for competitors.²

Here, the facts presented supports Mutual's assertion that Reckitt possesses monopoly power in the relevant market for ERG products: Reckitt possesses a significant percentage of the ERG market; little competition exists; Reckitt controls its development of ERG; and Reckitt's patent provides a barrier to entry for competitors.

3. Anticompetitive Conduct and Effects

In addition to demonstrating Reckitt's monopoly power, Mutual is also required to provide evidence of anticompetitive conduct—that Reckitt's power was used to foreclose competition. <u>U.S. v. Dentsply Int'l</u>, 399 F.3d 181, 191 (3d Cir. 2005). Anticompetitive conduct occurs when the defendant acquires or preserves its monopoly power through means other than on the merits. <u>See Broadcom</u>, 501 F.3d at 308. The challenged conduct "bar[s] a substantial number of rivals or severely restrict[s] the market's ambit." <u>Dentsply Int'l</u>, 399 F.3d at 191 (citing LePage's, Inc. v. 3M, 324 F.3d 141, 159-60 (3d Cir. 2003)).

Courts follow a three-part burden-shifting framework when examining anticompetitive conduct. First, the burden of proof of demonstrating anticompetitive conduct and effect rests on the plaintiff. Behrend, 2012 WL 1231794, at *19 (citing U.S. v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001)). If the plaintiff successfully establishes anticompetitive conduct, then the defendant must demonstrate a "procompetitive justification" for its conduct. Id. (citing Microsoft, 253 F.3d at 59). "A 'procompetitive justification' is a 'nonpretextual claim that [the monopolist's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." Id. (citing Microsoft, 253 F.3d at

² The Court notes, however, a patentee cannot be held liable for establishing and maintaining his patent monopoly where he does so within the permissible limits of his patent. <u>See Zenith Radio</u>, 395 U.S. at 136; <u>Sheet Metal Duct</u>, 2000 WL 987865, at *6.

59). The desire to maintain a monopoly market share or to thwart the entry of competitors would not be considered a valid business or procompetitive justification. See Le'Page's Inc., 324 F.3d at 165 (quoting Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1183 (1st Cir. 1994)). Once the defendant satisfies its burden, then the burden shifts back to the plaintiff to rebut the defendant's proffered justification, showing that it is pretextual or outweighed by its anticompetitive effects. See Behrend, 2012 WL 1231794, at *19; In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 679 (E.D. Pa. 2014).

Mutual argues that Reckitt's repudiation of the Settlement Agreement constitutes anticompetitive conduct. Reckitt contends that Mutual cannot demonstrate antitrust standing because it has not suffered antitrust injury. Mutual counters that it has indeed pleaded antitrust injury due to the anticompetitive effects of Reckitt's actions. Following the framework outlined above, Mutual has adequately pleaded anticompetitive effect and Reckitt's procompetitive justifications are outweighed by the anticompetitive effects of its actions.

a. Anticompetitive Conduct and Effect

The Third Circuit has outlined the factors relevant to establish antitrust standing as follows:

(1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

Barton & Pittinos, Inc. v. SmithKline Beecham Corp., 118 F.3d 178 (3d Cir. 1997) (citing In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165-66 (3d Cir. 1993)). The Third

Circuit "has refused to fashion a black-letter rule for determining standing in every case," and instead examines these many constant and variable factors on a case-by-case basis. Merican, Inc. v. Caterpillar Tractor Co., 713 F.2d 958, 964-65 (3d Cir. 1983). "Antitrust injury is a necessary but insufficient condition of antitrust standing." Barton & Pittinos, 118 F.3d at 182 (citing Lake Erie, 998 F.2d at 1166). Courts must also balance the other factors necessary to demonstrate antitrust standing.

i. Antitrust Injury

Because Reckitt mainly challenges Mutual's ability to demonstrate antitrust injury, the Court will begin its inquiry there.³ "An 'antitrust injury' is an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686, 695 (E.D. Pa. 2004) (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." Brunswick, 429 U.S. at 489. A plaintiff must show that the challenged conduct affected the prices, quantity or quality of goods or services. Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 728 (3d Cir. 1991). Additionally, the Court notes that "the existence of antitrust injury is not typically resolved through motions to dismiss." Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) (citing Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 876 (3d Cir. 1995)).

Mutual has pleaded facts to show that Reckitt's actions had an antitrust effect. Mutual alleges that Reckitt's repudiation of the Settlement Agreement constitutes an anticompetitive act,

³ Since the parties have not addressed the other factors relevant to determining antitrust standing, the Court will limit its analysis to whether Mutual has suffered antitrust injury.

which prevented Mutual from entering the ERG market with a generic product. <u>See</u> Compl. ¶ 27. As a result, Mutual asserts that Reckitt's actions have deprived Mutual and consumers of the economic benefits of increased supply and a lower-priced product. <u>See id.</u>; <u>cf. id.</u> at ¶ 34 (arguing that with the introduction of Perrigo's product, prices of Mucinex ERG decreased by approximately 16%, and with additional competition from Mutual's product, prices would have continued to decline). Mutual also alleges that Reckitt's repudiation of the Settlement Agreement has enabled Reckitt to extend its monopoly of the ERG market. Thus, Mutual pleads facts demonstrating both anticompetitive effect and antitrust injury.

ii. Reckitt's Procompetitive Justifications

Reckitt's procompetitive justifications for its actions are primarily limited to its patent rights. Reckitt counters that its patent lawfully excluded Mutual from the ERG market and challenges that Mutual's grievance amounts to nothing more than a breach of contract claim. Reckitt's Mem. of Law at 7-8. Reckitt further attempts to dismiss Mutual's claims by asserting that Mutual has not sustained antitrust injury due to the higher prices of Reckitt's ERG product because Mutual is not a cold sufferer or consumer of ERG. Reckitt's Reply at 5. Furthermore, Reckitt claims that its repudiation of the Settlement Agreement has not harmed competition because a third party, Perrigo, has entered the ERG market with a generic formulation. Id.

Therefore, competition exists in the ERG market.

Reckitt is correct when arguing that a patentee possesses the right to exclude competitors. See, e.g., Zenith Radio Corp., 395 U.S. at 135 ("A patentee has the exclusive right to manufacture, use, and sell his invention."); Sheet Metal Duct, 2000 WL 987865, at *6 ("[T]he very purpose of a patent is precisely to give a monopoly to the inventor for a finite time, and there can be no liability under the antitrust laws for the existence or maintenance of this statutory

monopoly."). However, Reckitt abridged its right to exclude Mutual from the market when granting Mutual a license to sell Reckitt's patented product prior to the expiration of the patent. Cf., Anton/Bauer, Inc. v. PAG, Ltd., 329 F.3d 1343, 1350 (Fed. Cir. 2003) ("[I]t is well settled that all or part of a patentee's right to exclude others from making, using, or selling a patented invention may be waived by granting a license . . . "); Ricoh Co., Ltd. v. Katun Corp., Civ. No. 03-2612, 2007 WL 2139576, at *16 (D.N.J. July 24, 2007) (same); Medtronic AVE, Inc. v. Advanced Cardiovascular Sys., Inc., 247 F.3d 44 (3d Cir. 2001) ("A patent license is in essence. . . a promise by the licensor not to sue the licensee." (citations and quotation marks omitted)). As such, when the conditions provided in the Settlement Agreement were satisfied, Mutual had the lawful right to enter the ERG market. Here, Mutual asserts that those conditions were met when 1) it did not acquire FDA approval to market the generic formulation for ERG; 2) a third party entered the market, therefore triggering the section of the Settlement Agreement providing for the parties to create a supply agreement; and 3) Mutual provided Reckitt written notice on October 24, 2013 that it was electing to purchase 600 mg of ERG product for resale from Reckitt. Compl. ¶¶ 22-24, 61-62, 67-68.

In addition to the arguments articulated above, Reckitt contends that its alleged breach of contract does not give rise to an antitrust violation because no antitrust duty to deal existed between the parties. Reckitt's Mem. of Law at 10. Reckitt relies on <u>Aspen Skiing Company v.</u>

<u>Aspen Highlands Skiing Corporation</u> for the rule that an antitrust duty to deal arises only when there has been a prior course of dealing between the parties and the alleged monopolist's actions make no economic sense absent the presence of an anticompetitive purpose. 472 U.S. 585 (1985).

Mutual counters that Reckitt's reliance on its patent is pretextual. See Mutual's Resp. in

Opp'n at 13. According to Mutual, when entering into the Settlement Agreement, Reckitt leveraged its patent to induce Mutual to keep its generic ERG product out of the market. <u>Id.</u> at 12; Compl. ¶ 28. By offering Mutual a patent license to enter the ERG market, Reckitt agreed to relinquish its rights to exclude Mutual from the ERG market under the patent. <u>See</u> Mutual's Resp. in Opp'n at 12. As such, now that the supply agreement has been triggered, Mutual argues that Reckitt's patent should no longer be used against Mutual. Furthermore, Mutual pleads that Reckitt's conduct falls outside the scope of the rights conferred by its patent, forces the parties into further litigation, and unlawfully extends Reckitt's monopoly enabling Reckitt to continue extracting monopoly profits. <u>Id.</u> at 13-14; Compl. ¶¶ 5, 28. As such, Mutual's allegations are not confined to refusal to deal arguments.

iii. Procompetitive Conduct Outweighed by Anticompetitive Effects

The monopolist's legitimate business justifications must outweigh the anticompetitive effect of its conduct to avoid liability. Microsoft, 253 F.3d at 58-59. Here, Reckitt has not discussed how its justifications outweigh any potential anticompetitive effect. Reckitt claims that Mutual cannot show anticompetitive effects of Reckitt's repudiation of the Settlement Agreement because Perrigo provides some competition in the ERG market to challenge Reckitt's monopoly.

However, the Court finds that Mutual has pleaded sufficient facts to demonstrate that Reckitt's conduct may indeed have anticompetitive effects and that those effects outweigh the procompetitive justifications proffered by Reckitt. The test for anticompetitive effect "is not total foreclosure." Dentsply Int'l, 399 F.3d at 191. All competition need not be removed. Id. Rather, the Court looks at "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Id.

Here, Mutual argues that no real competition exists to challenge Reckitt's monopoly. Specifically, Mutual pleads, "Perrigo's presence in the ERG market has been limited, barely denting Reckitt's ability to exercise its market power over the vast monopoly of the ERG market." Compl. ¶ 35. As a result, Reckitt maintains its monopoly in the ERG market and continues to benefit. Id. Mutual claims that Reckitt knew that Perrigo possessed a limited supply of the competing product, and therefore, acted intentionally to continue excluding Mutual from the ERG market. Mutual's Resp. in Opp'n at 5-6. This alleged conduct potentially extends beyond a breach of contract claim and plausibly constitutes anticompetitive behavior resulting in reduced competition for Reckitt in the ERG market and restricting the scope of the market. Therefore, the Court concludes that Mutual's allegations are sufficient to state a claim for antirust injury and that Reckitt's justifications are outweighed by the anticompetitive effects of its repudiation of the Settlement Agreement.

The Court declines to dismiss Mutual's Complaint on this ground at this stage of the litigation. This Court denies Reckitt's Motion to Dismiss Mutual's Sherman Act § 2 claim alleging monopolization.

B. Mutual's Attempted Monopolization Claim

A plaintiff bringing a claim for attempted monopoly "must prove that the defendant (1) engaged in predatory or anticompetitive conduct with (2) specific intent to monopolize and with (3) a dangerous probability of achieving monopoly." Queen City, 124 F.3d at 442 (quoting Spectrum Sports, 506 U.S. at 456). The requirements for both monopoly and attempted monopoly are similar, differing in the requisite intent and the necessary level of monopoly power to come dangerously close to success. See Coleman Motor Co. v. Chrysler Corp., 525 F.2d 1338, 1348 (3d Cir. 1975). A lesser degree of market power than that required for a completed

monopolization claim may successfully establish an attempted monopolization claim. <u>Behrend</u>, 2012 WL 1231794, at *19. Thus, the elements of Mutual's monopolization claims addressed above suffice for the analysis of its attempted monopolization claim, with the exception of the specific intent requirement. <u>Cf. Queen City</u>, 124 F.3d at 442 (stating that a court must inquire into the relevant product market and the defendant's economic power in that market).

In its Complaint, Mutual alleges that Reckitt possessed the specific intent to monopolize the market for ERG products. Specifically, Mutual argues, "Reckitt understands that if it had met its obligation under the Settlement Agreement . . . it would have lost its ability to freely extract monopoly profits. . ." Compl. ¶ 26. Additionally, Mutual claims, "Reckitt's specific intent in the anticompetitive acts . . . is and was to reduce competition and build a monopoly in the ERG market by denying Mutual access to ERG." Compl. ¶ 55. Given these pleadings, the Court concludes that Mutual's Complaint adequately states a claim for an attempted monopolization claim; namely, that Reckitt possessed the requisite intent to monopolize the ERG market. The Court denies Reckitt's Motion to Dismiss Mutual's attempted monopolization claim.

II. Mutual's State Law Claims

Mutual brings state law claims against Reckitt requesting damages and specific performance for breach of contract. Specifically, Mutual argues that Reckitt breached the terms of the Settlement Agreement wherein the parties agreed to execute a supply agreement in which Mutual would purchase from Reckitt ERG tablets corresponding to the third-party formulation. See Settlement Agreement §§ 5-6.

To prevail on a breach of contract claim under New York Law, "a plaintiff must establish '(1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages." Silicon Power Corp. v. Gen. Elec. Zenith Controls, Inc., 661 F. Supp. 2d 524, 542 (E.D. Pa. 2009) (quoting Harsco Corp. v. Segui, 91 F.3d 337, 348 (2d Cir. 1996)). Courts interpret contractual agreements according to their plain meaning. See, e.g., In re Nortel Networks Inc., 737 F.3d 265, 270 (3d Cir. 2013) (giving words in a contract their plain meaning); Lockheed Martin Corp. v. Retail Holdings, N.V., 639 F.3d 63, 69 (2d Cir. 2011) ("When an agreement is unambiguous on its face, it must be enforced according to the plain meaning of its terms." (citing S. Rd. Assocs., LLC v. IBM, 4 N.Y.3d 272 (2005))); Russack v. Weinstein, 291 A.D.2d 439 (2002) ("The interpretation of the terms of a written agreement that are clear and unambiguous is a matter of law for the court, and the court should construe the words and phrases used according to their plain meaning.").

Reckitt contends that Mutual's claims fail because 1) Mutual did not plead compliance with contractual conditions; 2) specific performance is inappropriate where money damages are available; 3) Mutual fails to allege irreparable harm to survive a specific performance claim; and 4) the Settlement Agreement and supply agreement are unenforceable. This Court finds none of these arguments compelling.

A. Mutual's Compliance with the Settlement Agreement

Reckitt challenges Mutual's breach of contract claim, asserting that Mutual failed to plead that it satisfied various conditions under the Settlement Agreement. Firstly, Reckitt alleges that Mutual did not provide notice requesting the supply of the correct ERG product in

⁴ The parties agreed that the Settlement Agreement and any dispute arising out of the Settlement Agreement would be governed by and construed in accordance with New York state law. Settlement Agreement § 28.

compliance with § 6(a) of the Settlement Agreement. Secondly, Reckitt argues that Mutual did not sign or serve the notice. Finally, Reckitt claims that Perrigo was not lawfully selling its generic guaifenesin product at the time Mutual made its demand.⁵

1. Notice Pursuant to the Settlement Agreement

Section 6(a) of the Settlement Agreement required that prior to executing a supply agreement, Mutual would notify Reckitt in writing of its election to purchase tablets of the guaifenesin product pursuant to § 5(b)(ii) of the Settlement Agreement. Settlement Agreement § 6(a). Section 5(b)(ii) provided that "Mutual . . . may purchase from [Reckitt] and [Reckitt] shall supply . . . tablets of the [Reckitt] Guaifenesin Product corresponding to such Third Party Formulation . . ." <u>Id.</u> at § 5(b)(ii). As such, according to the Settlement Agreement, Mutual could arrange to purchase from Reckitt the ERG product corresponding to the third-party ERG formulation. The relevant third-party formulation is Perrigo's generic ERG product.

On October 24, 2013, an agent for Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") wrote a letter to Reckitt on behalf of Mutual. <u>See</u> Reckitt's Mem. of Law, Ex. 6. According to the letter, Caraco had purchased Mutual in February 2013. <u>Id.</u> at Ex. 6, 2. In this letter, Mutual notified Reckitt that on November 23, 2011, Perrigo had received approval for 600 mg ERG product, a generic version of Mucinex. <u>Id.</u> Additionally, the letter stated that Perrigo launched its ERG product in April 2012. <u>Id.</u> The letter continued, "Since Mutual has not received FDA approval to market a Licensed Product that corresponds to Perrigo's product and in accordance

⁵ Reckitt also contends that another condition precedent included Mutual's acquisition of FDA approval to market the ERG product. Mutual disputes this and cites page 3 of the Settlement Agreement: "WHEREAS, as a result of this Agreement, Mutual's ability to enter into competition with the [Reckitt] Guaifenesin Products is not subject to its ability to obtain approval of the Mutual products." The Court declines to address this contractual dispute, as it involves questions of fact not proper for dismissal at this stage of litigation.

with Section 6(a) of the Agreement, Mutual elects to purchase [Reckitt's] 600 mg guaifenesin tablets for sale by Mutual." <u>Id.</u> Reckitt asserts that this notice was deficient because it failed to indicate that the product demanded by Mutual specifically corresponded to Perrigo's product.

However, the Court declines to dismiss Mutual's Complaint for this alleged deficiency. Reckitt's challenge involves questions of fact not properly addressed at the motion to dismiss stage. In its Complaint, Mutual alleges that it had provided Reckitt written notice that it had elected to purchase from Reckitt 600 mg ERG product for resale. See Compl. ¶¶ 22-24. The context of the demand letter could lead to this same conclusion. See Reckitt's Mem. of Law, Ex. 6. Accepting Mutual's factual allegations as true and making all inferences in the light most favorable to Mutual, the Court concludes that Mutual adequately pleaded that it requested from Reckitt an ERG product corresponding to Perrigo's product.

2. The Party Signing and Serving the Notice

Next, Reckitt argues that Caraco—not Mutual—signed and served the notice.

Consequently, Reckitt claims that Mutual did not make the request. However, as previously noted the Caraco representative indicated that Caraco purchased Mutual in February 2013 and stated that Mutual elected to purchase Reckitt's ERG product. See id. Therefore, Reckitt was put on notice that Mutual was making the request pursuant to the Settlement Agreement. The Court declines to dismiss Mutual's Complaint for this reason.

3. Perrigo's Lawful Sale of its ERG Product

Reckitt next argues that Perrigo was not lawfully selling its ERG product in October 2013 when Mutual made its demand. Reckitt refers to a gap in Perrigo's production of its generic ERG drug following Perrigo's launch in April 2012. See Reckitt's Mem. of Law 19; see also Compl. ¶

4. Mutual pleaded that the amount of generic ERG that Perrigo was able to manufacture was

limited, its ability to manufacture the drug was unreliable, and Perrigo failed to produce any generic ERG for a period following its launch date. Compl. ¶ 4.

However, Perrigo's difficulties in successfully or continuously producing and marketing its ERG product has no bearing on its launch date, which is the operative date triggering Mutual's rights under the Settlement Agreement. See Settlement Agreement § 5(b)(ii) ("If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation Mutual . . . may purchase from [Reckitt] tablets of the [Reckitt] Guaifenesin Product ... commencing no earlier than ninety (90) days after the corresponding Launch Date.") The Launch Date was defined in § 5(b)(i) as "the actual date of **first lawful commercial sale** of a formulation corresponding to the Licensed Product in such Third Party Launch Notice." (emphasis added). Accordingly, the date that Perrigo first lawfully sold its ERG product is the operative date here. The Settlement Agreement contains no requirement for the **continuous** sale of the third-party product and the Court will not read any such requirement into the party's agreement. See, e.g., Nortel Networks, 737 F.3d at 270. Mutual's Complaint pleads sufficient facts to show that Perrigo legally launched its ERG product prior to Mutual's demand on Reckitt, even if that launch was unsuccessful or disrupted. See Compl. ¶¶ 4, 22-24.

The Court denies Reckitt's Motion to Dismiss Mutual's Complaint for failure to plead that Mutual satisfied conditions precedent pursuant to the Settlement Agreement.

B. Specific Performance of the Settlement Agreement

In Count V of its Complaint, Mutual seeks specific performance of its agreement to purchase tablets from Reckitt corresponding to Perrigo's ERG product. Reckitt counters that specific performance is an inappropriate remedy here because money damages are available.

Additionally, Reckitt argues that Mutual has failed to demonstrate the requisite irreparable harm for specific performance.

"Specific performance should only be granted where the facts clearly establish the plaintiff's right thereto, where no adequate remedy at law exists, and where justice requires it."

<u>Utils., Inc. v. Blue Mountain Lake Assocs., L.P., 121 Fed. App'x 947, 948 (3d Cir. 2005)</u>

(quoting <u>Clark v. Pa. State Police</u>, 436 A.2d 1383, 1385 (1981) (quotation marks omitted)).

Damages may be an inadequate remedy "when there is no method by which the amount of damages can be accurately computed or ascertained." <u>Id.</u> at 949 (quoting <u>Clark</u>, 436 A.2d at 1385). For example, if "the subject matter of the agreement is unique or one such that its equivalent cannot be purchased on the open market" damages cannot be accurately ascertained.

<u>Id.</u> (quoting <u>Allegheny Energy, Inc. v. DQE, Inc., 171 F.3d 153, 160 (3d Cir 1999)); see also N.Y. U.C.C. § 2-716(1) ("Specific performance may be decreed where the goods are unique or in other proper circumstances.").</u>

Reckitt's arguments fail. Firstly, Mutual pled that the ERG product that it seeks from Reckitt is unique. See Compl. ¶¶ 30-33, 36. Moreover, considering that Reckitt holds the patent for the ERG product, Mutual is foreclosed from purchasing it on the open market. Therefore, damages may be an inadequate remedy to resolve the parties' dispute. See Blue Mountain, 121 Fed. App'x at 949.

Next, Reckitt's irreparable harm argument also fails. In § 26 of the Settlement

Agreement, the parties agreed that no adequate remedy at law existed for the damage which

either party might sustain for breach of the Settlement Agreement, and that the non-breaching

party would be entitled to specific performance. See Settlement Agreement § 26. In its

Complaint, Mutual pled that "no adequate remedy at law" exists and requested specific

performance. Compl. ¶¶ 36, 40, 70-71. Mutual also claimed that without specific performance it would continue to suffer irreparable harm. Compl. ¶ 72. Consequently, Mutual's claim for specific performance of contractual obligations survives and the Court denies Reckitt's Motion to Dismiss Mutual's request for specific performance.

C. Enforceability of the Settlement and Supply Agreements

Reckitt argues that the Settlement Agreement and supply agreement are invalid because they lack material terms. Pursuant to New York law, a contract provision is rendered unenforceable if the parties leave a material term for future negotiations. Trianco, LLC v. Int'l Bus. Machs. Corp., 271 Fed. App'x 198, 201 (3d Cir. 2008) (citing Joseph Martin, Jr. Delicatessen, Inc. v. Schumacher, 52 N.Y.2d 105, 109 (1981)). To be enforceable, "a contract must be definite with respect to essential terms." Fakhoury Enters., Inc. v. J.T. Distribs., No. 94 Civ. 2729, 1997 WL 291961, at *3 (S.D.N.Y. June 2, 1997). The essential terms in a contract for the sale of goods are quantity, price, and time and manner of delivery. Id. (quoting Judal Indus. v. Welsbach Elec. Corp., 138 A.D.2d 573, 574 (1988)). However, "a contract for the sale of goods will not fail for indefiniteness if the parties intended to make a contract and there is a reasonably certain basis for giving an appropriate remedy." <u>Judal</u>, 138 A.D.2d at 574 (citing U.C.C. § 2-204). Therefore, one or more undefined terms is not fatal to the contract. Where the parties' intent is clear and "there exists an objective method for supplying a missing term, the court should endeavor to hold the parties to the bargain." In the Matter of 166 Mamaroneck Ave. Corp., v. 151 E. Post Rd. Corp., 78 N.Y.2d 88, 91 (1991). Two ways to satisfy the definiteness requirement have been identified in Martin Delicatessen: (1) the four corners of the agreement could contain a methodology for determining the missing term; or (2) "the agreement could invite recourse to an objective extrinsic event, condition or standard on which the amount was

made to depend." 52 N.Y.2d at 110.

Here, Reckitt contends that the Settlement Agreement and supply agreement are missing terms specifying the quantity and identity of the product Mutual is to purchase. See Reckitt's Mem. of Law 21. Reckitt claims that absent these terms, the contracts are unenforceable agreements to agree. However, Reckitt has not pointed the Court to the allegedly defective sections of the Settlement Agreement and supply agreement to support its arguments. Moreover, Mutual's Complaint states that Mutual identified the product it requested from Reckitt: "On October 24, 2013, Mutual provided Reckitt written notice that . . . it was electing to purchase from Reckitt 600 mg ERG product for resale. . . ." Compl. ¶ 24; see also Reckitt's Mem. of Law, Ex. 6 at 2. Regarding the quantity of the product, § 2.3 of the supply agreement indicates,

At least ninety (90) days prior to the Mutual Launch Date for a Product, Mutual shall make a good faith estimate of Mutual's projected requirement of such Product for delivery Mutual shall give [Reckitt] Mutual's good faith estimate of Mutual's projected requirements of such Product for delivery

Settlement Agreement, App. C § 2.3, Supply Agreement. Given these provisions, Mutual argues, and the Court agrees, that a methodology to determine the quantity of ERG product requested was provided. See Mutual's Resp. in Opp'n at 23.

Reckitt next argues that the Settlement Agreement and supply agreement should not be construed as requirements contracts because the agreements lack exclusivity. See Reckitt's Mem. of Law at 22-23. Mutual counters that its Complaint adequately pleads facts demonstrating that Reckitt is Mutual's only source of the ERG product. See Mutual's Resp. in Opp'n at 23.

In a requirements contract, "the buyer agrees to purchase his requirements exclusively from the other party to the contract." Embedded Moments, Inc. v. Int'l Silver Co., 648 F. Supp. 187, 192 (E.D.N.Y. 1986). The quantity of the good to be delivered to the buyer is determined by

the good faith requirement of the parties. <u>See E. Dental Corp. v. Isaac Masel Co., Inc.</u>, 502 F. Supp. 1354, 1363-64 (E.D. Pa. 1980). The quantity term need not be enumerated, but some writing indicating that the quantity to be delivered is the buyer's requirement should be provided. <u>Id.</u> at 1364. Thus, the buyer's requirement at the time of contracting may be uncertain.

Here, Mutual counters Reckitt's challenge by claiming that a requirements contract does not obligate the seller to exclusively supply the buyer with its product. The Court agrees. In a requirements contract, the buyer commits to exclusively purchase from the seller all of a specified product. See, e.g., Embedded Moments, 648 F. Supp. at 192; Int'l Commercial Res., Ltd. v. Jamaica Pub. Servs. Co., Ltd., 612 F. Supp. 1153, 1155 (S.D.N.Y. 1985). The seller is not obligated to sell exclusively to that one buyer, and therefore, Mutual was not obligated to plead reciprocal exclusivity.

Mutual claims that its Complaint indicated that the parties agreed that Mutual would only purchase from Reckitt. Making all inferences in favor of Mutual, the Court concludes that Mutual has sufficiently pleaded facts demonstrating the existence of a requirements contract. Since Reckitt owned the patent for the ERG product, Mutual was unable to purchase from other suppliers. Mutual pleads that it was unable to sell a generic product manufactured by Reckitt due to Reckitt's refusal to supply it with the generic ERG formulation. Compl. ¶ 39. Furthermore, Mutual states, "Only Reckitt can manufacture ERG that precisely matches the specification of the Mucinex® product." Id. As such, one could conclude that Reckitt provided Mutual with the only channel for purchasing Reckitt's ERG product and the Settlement Agreement and supply agreement created requirements contract.

III. Mutual's Claim for Declaratory Judgment

Reckitt moves to dismiss Mutual's claim for declaratory judgment for lack of ripeness.

The Court will grant Reckitt's Motion in part.

The judicial power of the United States is limited to the adjudication of a case or controversy. U.S. Const. Art. III § 2. A justiciable case or controversy must be ripe for the court's review. Market St. Sec., Inc. v. NASDAQ OMX PHLX LLC, 900 F. Supp. 2d 529 (E.D. Pa. 2012). "A claim is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas v. U.S., 523 U.S. 296, 300 (1998) (quoting Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568, 580-81 (1985)).

Ripeness is a matter of degree, especially in declaratory judgment actions because they are usually sought before a completed injury has occurred. Pittsburgh Mack Sales & Serv., Inc. v. Int'l Union of Operating Eng'rs, Local Union No. 66, 580 F.3d 185, 190 (3d Cir. 2009) (quoting Pic-A-State Pa., Inc. v. Reno, 76 F.3d 1294 1298 (3d Cir. 1996)).

The Third Circuit has established a test to determine whether a declaratory judgment action is ripe through examining: "1) the adversity of the parties' interest, 2) the conclusiveness of the judicial judgment, and 3) the practical help, or utility of that judgment." Market St., 900 F. Supp. 2d at 533 (citing Step-Saver Data Sys., Inc. v. Wyse Tech., 912 F.2d 643, 647 (3d Cir. 1990)). The Court will review Mutual's declaratory judgment action in accordance with these factors.

A. Adversity of Interest

"[A] potential harm that is 'contingent' on a future event occurring will likely not satisfy [the adversity of interest] prong of the ripeness test." <u>Pittsburgh Mack</u>, 580 F.3d at 190 (citing <u>Step-Saver</u>, 912 F.2d at 647-48). However, the plaintiff need not have suffered a completed harm, but must demonstrate that the probability of the feared future event occurring is real and substantial, of sufficient immediacy and reality to warrant the issuance of a declaratory

judgment. <u>Id.</u> (quoting <u>Armstrong World Indus., Inc. v. Adams</u>, 961 F.2d 405, 412 (3d Cir. 1992)). If intervening events would remove the potential for harm, then the controversy becomes speculative. <u>Market Street</u>, 900 F. Supp. 2d at 533 (citing <u>Presbytery of N.J. of Orthodox</u> <u>Presbyterian Church v. Florio</u>, 40 F.3d 1454, 1463 (3d Cir. 1994)).

In this case, Mutual seeks an Order declaring the validity of the Settlement Agreement and Reckitt's duty to supply Mutual with authorized generic versions of its Mucinex ERG products at the time third-party manufacturers launch products pursuant to various Abbreviated New Drug Applications ("ANDA"). Compl. ¶ 82. This Order would include Reckitt's duty to supply an authorized generic version of Mucinex® 600 mg ERG. Id. However, Mutual goes beyond the ERG product at issue—the formulation corresponding to Perrigo's generic product—and requests declaratory judgment as to any other third-party product corresponding to the Mucinex® products. Mutual claims that other manufacturers, Watson and/or Aurobindo, have filed ANDAs seeking to sell generic products corresponding to Mucinex® products. Id. at ¶ 80. Mutual suggests that these other third parties will receive approval to sell their generic products, thereafter triggering the supply agreement. Id. at ¶¶ 80-82; see also Mutual's Resp. in Opp'n at 24.

Mutual's claims pertaining to third parties other than Perrigo are speculative. Prior to legally launching their generic formulations of the various Mucinex® products, the other third parties will need to obtain approval of their ANDAs. See 21 U.S.C. § 355(j); see also Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223, 2227-28 (2013) (discussing the drug-regulatory framework and the process for ANDA approval). The Court cannot speculate that those third parties will successfully obtain FDA approval. Moreover, pursuant to the Settlement Agreement, Mutual will also be required to give Reckitt written notice of its demand for those

other products. These are all intervening events that may or may not materialize. Therefore, the risk of harm to Mutual is unknown and the Court concludes that Mutual has failed to present sufficient adversity of interest between the parties. Given that Mutual has failed to satisfy the first factor in the test for declaratory judgment with respect to the third-party drugs other than Perrigo's formulation, the Court concludes that declaratory judgment as to those drugs is not warranted.

As to Perrigo's 600 mg ERG product, however, the Court concludes that Mutual has pleaded sufficient facts to demonstrate adversity of interest. Mutual has indeed pleaded that it suffered harm from Reckitt's alleged repudiation of the Settlement Agreement following Perrigo's launch of its ERG product. The Court will continue its inquiry as it relates to Perrigo's 600 mg ERG formulation.

B. Conclusivity

The next step in determining ripeness is to examine "the conclusiveness of the judicial judgment." Pittsburgh Mack, 580 F.3d at 190 (citing Step-Saver, 912 F.2d at 647). "A declaratory judgment is conclusive if it definitively decides the rights of the parties." Market St., 900 F. Supp. 2d at 534 (citing Step-Saver, 912 F.2d at 649 n. 9). Judicial action should "amount to more than an advisory opinion based upon a hypothetical set of facts." Pittsburgh Mack, 580 F.3d at 190 (citing Presbytery of N.J., 40 F.3d at 1468). Here, Mutual presents the Court with a actualized facts regarding Perrigo's product launch. Declaratory judgment as to Perrigo's ERG product would be conclusive and the Court retains jurisdiction.

C. Utility

The third and final step in evaluating ripeness looks to "the practical help, or utility" of the court's judgment. <u>Pittsburgh Mack</u>, 580 F.3d at 191 (quoting <u>Step-Saver</u>, 912 F.2d at 647).

Here, Mutual asserts that a declaratory judgment would be useful so that it will know whether it can plan market entry. Mutual's Resp. in Opp'n at 24. Because an actual controversy exists pertaining to Perrigo's product, the Court agrees that declaratory judgment would be useful and practical for Mutual's planned market entry.

In conclusion the Court grants Reckitt's Motion to Dismiss Mutual's claim for declaratory judgment as to third-party formulations other than Perrigo's 600 mg ERG formulation and denies Reckitt's Motion as to Perrigo's ERG product.

CONCLUSION

For the foregoing reasons, the Court will deny Reckitt's Motion to Dismiss Mutual's Complaint with respect to Mutual's antitrust and state law claims. The Court will grant Reckitt's Motion to Dismiss Mutual's claim for declaratory judgment as to all third-party formulations of Mucinex® other than Perrigo's 600 mg ERG product, but deny Reckitt's Motion as to Perrigo's 600 mg ERG product, which is the primary subject of Mutual's Complaint.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

URL PHARMA, INC., ET AL.,

:

Plaintiffs, : CIVIL ACTION

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v. : 15-505

:

RECKITT BENCKISER, INC.,

:

Defendant.

ORDER

AND NOW, this 25th day of August, 2015, upon consideration of Defendant Reckitt Benckiser, Inc.'s ("Reckitt") Motion to Dismiss Plaintiffs' Complaint Pursuant to Rules 8(a) and 12(b)(6) (Doc. 20), Plaintiffs URL Pharma, Inc., Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc.'s (collectively "Mutual") Response in Opposition to Reckitt's Motion to Dismiss (Doc. 21), Defendant Reckitt's Reply Memorandum of Law in Further Support of Its Motion to Dismiss (Doc. 24), and all other briefs, exhibits, and papers herein, IT IS HEREBY ORDERED AND DECREED as follows:

- 1. Reckitt's Motion is **DENIED** as to Mutual's antitrust and state law claims;
- 2. Reckitt's Motion is **DENIED** as to Mutual's claim for declaratory judgment pertaining to Perrigo's 600 mg ERG formulation of Reckitt's ERG product;
- 3. Reckitt's Motion is **GRANTED** as to Mutual's claim for declaratory judgment relating to all other third-party formulations of Reckitt's Mucinex® product.

BY THE COURT:

/s/ Petrese B. Tucker

Hon. Petrese B. Tucker, C.J.